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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,307	11/26/2001	Joel R. Haynes	APF 41.20	5358

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,307	HAYNES ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24,26-29,32-53,55,57-60 and 63-82* is/are pending in the application.

4a) Of the above claim(s) *63-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24,26-29,32-53,55,57-60 and 63-82* is/are rejected.

7)☐ Claim(s) *29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/25/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22,24,26-29, 32-53,55,57-60, and new claims 81-82 all recite a new combination of claim limitations based upon Applicants amended claims, and are under consideration. Claims 63-80 stand withdrawn from consideration as being directed to a non-elected invention. Claims 23,25,30-31, 54,56,61-62 have been canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's arguments with respect to claims 1-22,24,26-29, 32-53,55,57-60, and new claims 81-82 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Claim 29 is objected to because of the following informalities: Claim 29 recites the term "about 3:M"; the meaning of the term ":M" appears to be a typo, as the meaning of this term is unclear. Appropriate correction is required.

Please Note: All of the claims have been amended to recite "coated onto core carrier", and a "promoter active in a mammalian cell" a combination of claim limitations not previously recited in the claims; the newly submitted combination of claim limitations has necessitated new grounds of rejection as the combination of claims limitations have not been previously considered on the record prior to the last Amendment submitted by Applicant.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-8,11-14,16,18-22,24,26-27,32-39.42-45,47,49-53,55,57-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Fitzgerald et al (US Pat. 6,423,515 B1, effective filing date November 6, 1996).

(Instant claims 1, 32, 44) Fitzgerald et al disclose the instantly claimed invention directed to compositions that comprise first (see claims 1, that includes fragments (domain A is SEQ ID NO 2 amino acids 400-613, but claims embodiments that are truncated through the recitation of the phrase 80% identity with SEQ ID NO 2, and teaches that a fragment of amino acids 400-600 (see col. 24, lines 39-43) which evidences ADP-ribosylating activity and shares greater than 90% identity with SEQ ID NO 2) of Pseudomonas aeruginosa exotoxin A (an ADP-ribosylating toxin), together with a

and second nucleic acid sequence that encodes a fragment of domain B (see Fitzgerald et al, claim 1, paragraph (b)) together with

a third nucleic acid that is a heterologous sequence that encodes for a cell recognition domain and therefore does not comprise a bacterial leader sequence peptide at the 5' end of the coding sequence.

Coated onto a core carrier (see col. 27, lines 34-50, "particle mediated transfection and intracellular expression" and col. 31, lines 18-37)

(Instant claim 2, 33) present in a single nucleic acid construct (see col. 27, lines 1-3 (mammalian cells).

(Instant claim 3,34, 47,51) the nucleic acid construct is a plasmid vector (see col. 28, line 6 "cells transformed by the plasmids")

(Instant claim 4,35) comprises a transcriptional control element (see col. 27, lines 14-22 and lines 57-67; col. 32, lines 44-51).

(Instant claim 5,36) heterologous promoter (see col. 27, lines 66-67 and col. 28, lines 1-3).

(Instant claim 6-7, 18-21; 37-39, 49-52) the first and second sequences are present on separate nucleic acid constructs (see Figure 1B, combinations of two different plasmids; col. 31, lines 25-25 "inserted into any number of well known vectors")

(Instant claim 8) coding regions are obtained or derived from the same bacterial ADP-ribosylating exotoxin (Pseudomonas aeruginosa exotoxin A, an ADP-ribosylating exotoxin (see title, Figure 3A was used as the source for the first and second nucleic acids).

(Instant claim 11-12; 42-43) detoxified (see col. 24, lines 41-43 "ADP ribosylating activity is eliminated" through deletion of the amino acid at position 553 ("ΔE553"), see col. 14, lines 25-38.

(Instant claim 13) wherein the C-terminal lacks KDEL or RDEL, wherein native PE exotoxin A comprises REDLK (see col. 24, line 28), which is not either one of KDEL or RDEL and therefore lacks the recited sequences KDEL or RDEL.

(Instant claim 14, 16, 20-21, 45, 47) an antigen of interest (see claim 1 (a) "domain of between 10-1500 amino acids" and claim 5 "activatable sequence is cleavable by prostate specific antigen or urokinase"; see col. 28, line 61 (includes "biotin and avidin") and see col. 6, lines 58-60).

(Instant Claim 22, 53): particulate form (liposome or particle mediated transfection (see col. 27, lines 37-38; col. 31, lines 39-59).

(Instant claims 24, 26, 55,57) pharmaceutically acceptable vehicle or excipient (see col. 13, lines 13-32 (transdermal), the size including 1 um to approx. 5 um (see col. 34, lines 49-58).

(Instant claim 27,58) the core carrier particle is a metal (see US Pat. 5,271,961 which is incorporated by reference at col. 35, line 4, which discloses metal carrier particles, '961, claim 17).

6. Claims 1-5,8-17,20-22,24,26-29, 32-36, 39-43,45-48,51-53,55,57-60,81-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Glenn et al (US Pat. 5,980,898) as evidenced by US Patents incorporated by reference(US Pat. 5,593,972 and US Pat. 4,945,050)

(Instant claims 1, 32) Glenn et al disclose the instantly claimed invention directed to a multivalent (see col. 8, line 33) transcutaneuous (see col. 13, lines 61-67) vaccine (see abstract; col. 4, lines 24-28) composition that comprises:

a first nucleic acid (genetic immunization, col. 14, line 13; col. 8, lines 3-5; col. 11, lines 41-49; cholera toxin A:B dimmer (see col. 9, lines 62-67), ADP-ribosylating toxin A subunit fragment (see col. 9, lines 61-67 and col. 10, lines 1-4) which have been genetically detoxified into toxoids (see col. 10, lines 61 and col. 11, lines 17-30 "inactivating the catalytic activity of

the ADP-ribosyl transferase by genetic deletion", wherein a genetic deletion would result in an A subunit fragment portion of the whole)

and second nucleic acid sequences that encode a B subunit of a ADP-ribosylating exotoxin wherein the B subunit (derivatives thereof (see col. 10, line 33; and subunits, and toxoids thereof (see col. 8, lines 42-44) ,

a third nucleic acid that is a heterologous sequence that encodes for a heterologous coding sequence for an antigen a pathogen, specifically a bacteria, a virus and/or a parasite (see col. 9, lines 4-32 and col. 14, lines 13-16 antigen (of a pathogen), the adjuvant (exotoxin first and second nucleic acids that encode both the A and B components) .

(**claims 1, 27-29, 32, 59-60 and new claims 81-82**) Coated onto a core carrier (see col. 14, line 14, as evidenced by US Pat. 5,593,972 and US Pat. 4,945,050 (see '972, col. 20, lines 32-36) which discloses "particle mediated transfection and intracellular expression", wherein the particles are coated (see '050, col. 6, line 36) on a gold, tungsten, ferrite, polystyrene, or latex particle(see '050, claims, 5-7) and are about 0.1 to 4 micrometers in diameter.

(Instant claim 2, 33) present in a single nucleic acid construct (see col. 14,lines 22-23.

(Instant claim 3,34, 47,51-52) the nucleic acid construct is a plasmid vector (see col. 11, lines 45-46).

(Instant claim 4,35) comprises a transcriptional control element (see col. 14,lines 13-29).

(Instant claim 5,36) heterologous promoter (see col. 14, lines 13-19).

(Instant claim 8,39) coding regions are obtained or derived from the same bacterial ADP-ribosylating exotoxin (each AB toxin is considered col. 9, lines 62-67 and col. 10, lines 1-4).

Instant claim 9, 40: cholera toxin (see col. 9, line 67)

Instant claim 10, 41: E.coli heat labile enterotoxin (see col. 9, line 67).

(Instant claim 11-12; 42-43) detoxified (see col. 10, line 61-67 and col. 11, lines 20-25)

(Instant claim 13) wherein the C-terminal lacks KDEL or RDEL, wherein native PE exotoxin A comprises REDLK (see col. 9, line 66), which is not either one of KDEL or RDEL and therefore lacks the recited sequences KDEL or RDEL.

(Instant claim 14-17, 20-21, 45-48) an antigen of interest (see col. 9, lines 5-31 and col. 14, lines 15-16).

(Instant Claim 22, 53): particulate form (liposome or particle mediated transfection (see col. 14,line 14).

(Instant claims 24, 26, 55,57) pharmaceutically acceptable vehicle or excipient (see col. 14, lines 1-8 and col. 14, lines 23-29; col. 9, lines 43-56; col. 5, lines 30-37)).

(Instant claim 27,58) the core carrier particle is a metal (see US Pat. 5,593,972 which is incorporated by reference at col. 14, line 13, which discloses metal carrier particles).

The reference inherently anticipates the instantly claimed invention.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various US Patents have been sited on the US PTO 892 that teach recombinant ADP-ribosylating toxins, nucleic acid vectors that comprise nucleic acids for ADP-ribosylating toxins, and methods of administering nucleic acids by a transdermal or transmucosal route of administration.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
January 7, 2005

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